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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,103

04/07/2008

Pascal Paganon

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1061

25207

7590

10/07/2009

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EXAMINER

GRAHAM, BRIAN J

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

10/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/598,103	<b>Applicant(s)</b> PAGANON ET AL.	
	<b>Examiner</b> BRIAN GRAHAM	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/29/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-8, 11, 16-17, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai *et al.*, hereinafter referenced as “Lai” (United States Patent Number 4,739,758).

Lai discloses an expandable intragastric balloon (10) comprising an outer casing (21) and an inflation chamber (22) within the casing, both of which are flexible enough to pass from a reduced-volume shape into the stomach of a patient (see Figure 6).

Regarding claims 6-8, Lai discloses the inflation chamber is made of a low gas permeable EVA (col. 3, lines 41-54).

Regarding claim 11, Lai discloses coating the outer casing with silicone rubber to provide additional bio-compatibility (col. 1, lines 60-68).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 12-14, and 22 are rejected under 35 U.S.C. 103 as being unpatentable over Lai in view of Gau *et al.*, hereinafter referenced as “Gau” (United States Patent Number 5,084,061).

While Lai fails to disclose an elastomer material, Gau discloses an intragastric balloon which is made of the elastomer silicone (elastomeric shell 22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflation chamber and/or shield of Lai with the elastomeric material of Gau in order to provide flexibility while retaining low gas permeability.

Claims 9-10 are rejected under 35 U.S.C. 103 as being unpatentable over Lai in view of Garren *et al.*, hereinafter referenced as “Garren” (United States Patent Number 4,899,747).

While Lai fails to disclose the shield of inner pouch being made of polyurethane, Garren discloses an intragastric balloon wherein the combined inflation pouch and shield are made of polyurethane (col. 3, lines 30-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inflation chamber and/or shield of Lai with the polyurethane material of Garren in order to provide flexibility while retaining low gas permeability.

Claims 15, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai in view of Paganon (United States Patent Application Publication Number 2007/0135829).

While Lai fails to disclose the inflation chamber and the outer layer being movable relative to each other, Paganon discloses an intragastric bag apparatus which utilizes an inflation chamber (10) separate from the outer layer (8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the separate chamber construction of Paganon in the balloon of Lai in order to provide a means of alternating the balloon between two varying inflated states.

Paganon further discloses coating the balloon in parylene (abstract).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN GRAHAM whose telephone number is (571)270-7484. The examiner can normally be reached on Monday - Friday 8:00 am-5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B.J.G./

September 29, 2009

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734